

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC., et al.,
Plaintiffs,
v.
ARIOSA DIAGNOSTICS, INC, et al.,
Defendants.

Case No. [12-cv-05501-SI](#)

**ORDER RE MOTIONS FOR
SUMMARY JUDGMENT, MOTIONS
TO STRIKE, AND MOTION TO
PRECLUDE TESTIMONY**

Re: Dkt. Nos. 395, 400, 401, 416, 442

Filed Under Seal

Before the Court are the following motions: special motion to strike and motion for summary judgment, filed by plaintiffs Verinata Health, Inc. and Illumina, Inc.; and motion for summary judgment, motion to preclude the testimony of Gregory Cooper, and motion to strike portions of the corrected expert report and deposition testimony of Gregory Cooper, filed by defendant Ariosa Diagnostic, Inc.¹ After hearing argument and considering the parties' materials, the Court rules as follows.

BACKGROUND²

I. Factual Background

This consolidated patent infringement action currently involves two patents, U.S. Patent No. 8,318,430 ("the '430 patent") and U.S. Patent No. 7,955,794 ("the '794 patent" and, together with the '430 patent, the "patents-in-suit"). Illumina and Verinata accuse Ariosa's Harmony™

¹ Defendant's motion to preclude testimony of plaintiffs' damages expert (Dkt. No. 418) will be addressed in a separate order.

² All docket numbers refer to Case No. 12-cv-5501, unless otherwise noted.

Prenatal Test of infringing the patents-in-suit. Ariosa filed counterclaims seeking, among other things, declaratory relief of invalidity and non-infringement of both patents-in-suit. Only the details of Illumina's '794 patent are at issue in the pending motions.

A. The '794 Patent

The '794 patent, titled "Multiplex Nucleic Acid Reactions," is "directed to a variety of multiplexing methods used to amplify and/or genotype simultaneously." The '794 Patent, Abstract.³ The patent was filed in 2002 and issued to Illumina in June 2011. The invention allows for the detection of over 100 different target sequences by introducing probes with complementary sequences into a sample and observing whether hybridization occurs. Claim 1 of the '794 patent—the only independent claim—recites the following:

1. A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising:

a) providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;

b) contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises:

i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and

ii) a target specific domain, such that different double-stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample;

c) removing unhybridized probes;

d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes;

e) contacting said modified probes with:

³ See Declarations of Sandra L. Haberny in support of Ariosa's Motions ("Haberny Decl.") (Dkt. Nos. 404, 437, 451), Ex. 1 ("The '794 Patent").

- i) at least a first primer that hybridizes to said universal priming site;
- ii) NTPs; and
- iii) an extension enzyme;

wherein said different modified probes are amplified and forming different amplicons;

f) immobilizing said different amplicons to a second solid support, and

g) detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences.

The '794 Patent, 68:44-69:12.

The Court has construed “modified probe” to mean: “an enzymatically altered polynucleotide which contains a universal priming site and is capable of substantially hybridizing to a target sequence.” Claim Construction Order (Dkt. No. 199) at 9. It also construed “wherein said different modified probes are amplified and forming different amplicons” to mean: “wherein the different modified probes are replicated, in whole or in part, to yield amplification products of each of the different modified probes.” *Id.* at 11.

B. The Parties

Illumina develops, manufactures, and markets life science tools and integrated systems for large-scale analysis of genetic variation and function. Illumina’s Amended Complaint (“AC”) (No. 15-cv-2216, Dkt. No. 17) ¶ 4. Ariosa is a “commercial-stage molecular diagnostics company” that is “focused on research, evaluation, and development in the field of non-invasive prenatal testing for chromosomal abnormalities in a fetus.” Ariosa’s Answer (Dkt. No. 283) ¶ 10.

In 2010, Illumina made an equity investment in Ariosa. Illumina’s Answer (No. 14-cv-1921, Dkt. No. 108) ¶ 18. In March 2011, Ariosa gave Illumina an investor presentation on Ariosa’s new developments, including confidential details regarding a sequencing-based non-invasive prenatal DNA test. Haberny Decl., Exs. 47, 48. One of the slides used in Ariosa’s presentation was its “Freedom to Operate” slide, which included the patent family entitled “Multiplex nucleic acid reactions” by “Oliphant et al.” *Id.*, Ex. 48 at 23. Ariosa asserts that the ‘794 patent, which was filed in 2002 and issued in June 2011, is part of this patent family. Def.’s

1 Opp'n to Pls.'s MSJ at 12. Therefore it is Ariosa's view that Illumina became aware of the
2 relationship between Ariosa's test product and the '794 patent at that meeting.

3 In July 2011, Ariosa and Illumina began negotiating a sale and supply agreement.
4 Haberny Decl., Ex. 63. In January 2012, seven months after the '794 patent issued, Ariosa entered
5 into a three-year Sale and Supply Agreement, under which Illumina agreed to supply specific
6 consumables, hardware, and software to Ariosa. Declaration of Derek C. Walter ISO Pls.'
7 Motion to Strike ("Walter MTS Decl.") (Dkt. No. 402), Ex. 6 ("Agreement"). The Agreement
8 provided Ariosa with a non-exclusive license to Illumina's "Core IP Rights in Goods," but not
9 Illumina's "Secondary IP Rights in Goods." *Id.* "Customer Field of Use" was defined as "(a)
10 commercial services for the cell-free detection of fetal chromosomal abnormalities having a length
11 greater than one megabase by pre-natal screening using DNA sequencing, . . . and (b) internal,
12 non-commercial experimental research[.]" *Id.* at 2. The Agreement required Ariosa to exclusively
13 use Illumina's "Goods" to perform all of its sequencing activities in subpart (a) of the Customer
14 Field of Use. *Id.* § 2.

15 Before executing the Agreement, it appears that Illumina never suggested that Ariosa
16 needed to license the '794 patent to operate Ariosa's test. Haberny Decl., Ex. 42 at 193:3-10.
17 Section 3(c) of the Agreement, however, explicitly stated that "[n]o right or license under any
18 Illumina Intellectual Property Rights, including without limitation Secondary IP Rights in Goods,
19 is or are granted, expressly or by implication, to Customer under this Agreement except as
20 expressly stated in Section 3(a)." Agreement § 3(c).

21 By May 2012, Ariosa launched a sequencing-based, non-invasive prenatal DNA test called
22 the Harmony™ Prenatal Test, which used materials supplied by Illumina. Ariosa's Answer (Dkt.
23 No. 283) ¶ 11. In January 2013, Illumina announced that it was acquiring Ariosa's competitor
24 Verinata, which offers the verifi® prenatal test that similarly "analyze[s] cell-free DNA
25 circulating in the blood of a pregnant woman by DNA sequencing in order to determine whether a
26 fetus is at risk of having an abnormal number of chromosomes[.]" *See id.* ¶ 30; Haberny Decl., Ex.
27 43; Verinata's Fourth Amended Complaint ("FAC") (Dkt. No. 349) ¶ 9.

1 Soon after the acquisition announcement, Illumina and Ariosa began engaging in
2 discussions regarding amendment of the Sale and Supply Agreement. Answer to Counterclaims
3 (No. 14-cv-1921, Dkt. No. 108) ¶ 34; Haberny Decl., Exs. 51, 52, 65. Around this time, Illumina
4 told Ariosa that the “Customer Field of Use” in the Sale and Supply Agreement did not include
5 fetal sex determination. Illumina’s Answer (No. 14-cv-1921, Dkt. No. 108) ¶ 35. For instance, in
6 January 2014, Illumina sent Ariosa a letter stating that Ariosa had breached the Sale and Supply
7 Agreement by: (1) not “identifying and ensuring that it has all Secondary IP Rights in Goods that
8 are necessary for it to use the Goods in the Customer Field of Use”; and (2) by using the Harmony
9 test to determine and report fetal gender, which Illumina asserted was outside the Customer Field
10 of Use licensed under Illumina’s Core IP Rights in Goods. Haberny Decl., Ex. 51; *see also id.*,
11 Ex. 52.

12 On March 24, 2014, Ariosa filed documents with the Securities and Exchange Commission
13 to prepare for an initial public offering (“IPO”). Declaration of Derek C. Walter ISO Pls.’ MSJ
14 (“Walter MSJ Decl.”) (Dkt. No. 396), Ex. 5. On April 24, 2014, Illumina sent a letter to Ariosa
15 revoking any offers to extend the Sale and Supply Agreement. Haberny Decl., Ex. 52. That
16 evening, as Ariosa’s team gathered to launch their IPO “roadshow” set for the following day, the
17 Ariosa team received a call from counsel alerting them to Illumina’s letter. Walter MSJ Decl., Ex.
18 28 at 31-34; Haberny Decl., Ex. 41 at 197:6-25. Ariosa understood the letter as stating that it was
19 in breach, there would be no further negotiations with Illumina, and the Agreement would
20 terminate in a few months. Walter MSJ Decl., Ex. 28 at 33:1-8. Subsequently, Ariosa decided not
21 to proceed with the IPO launch. *Id.* at 33:15-18, 34:6-10. Illumina filed a patent infringement suit
22 against Ariosa on April 25, 2014, accusing the Harmony Test of practicing the ’794 patent. No.
23 14-cv-1921, Dkt. No. 1. It is disputed whether Ariosa officially cancelled the IPO before or after
24 the lawsuit was filed. *See* Haberny Decl., Ex. 41 at 200:8-17; Pls.’ Mot. for Summary Judgment
25 (Dkt. No. 395) at 10.

C. The Harmony™ Prenatal Test

There are two versions of the Harmony™ Prenatal Tests accused of infringing the '794 patent. The first, "Harmony V1," is the older version, where data was generated on a sequencing platform using Illumina sequencers. Ariosa later released a second version, "Harmony V2," which generates data on an Affymetrix microarray. The Harmony Test analyzes certain genetic loci on chromosomes 13, 18, 21, X, and Y in cell-free DNA ("cfDNA") from a pregnant woman, using a biochemical assay called Digital Analysis of Selected Regions ("DANSR"). It generates data that is then evaluated using the Fetal-fraction Optimized Risk of Trisomy Evaluation ("FORTE") algorithm. The data is used to detect fetal aneuploidies (an abnormal number of chromosomes), which can lead to conditions such as Patau syndrome (chromosome 13), Edwards syndrome (chromosome 18), and Down syndrome (chromosome 21).

In Harmony V2,⁴ cfDNA is labeled with biotin and then "locus specific DANSR oligos [oligonucleotides] are added to form double-stranded complexes of oligos annealed to the cfDNA fragments containing their respective complementary loci." Haberny Decl., Ex. 7 at 15. A trio of oligos is used

[REDACTED]

⁴ The relevant process of Harmony V1 is disputed and included in the discussion section below.

The DANSR oligos anneal (or hybridize) to the cfDNA to form double-stranded complexes and streptavidin beads are added. Afterward, an enzyme called ligase chemically joins the three DANSR oligos that have hybridized with each target sequence, creating a single oligo called the “ligation product.” Def.’s MSJ at 5; *see also* Pls.’s MSJ Opp’n at 5; Corrected Cooper Report ¶¶ 256-257. The ligation product is then eluted, or “released from hybridization so it becomes a single stranded in solution phase molecule.” Haberny Decl., Ex. 6 at 65:6-17; Corrected Cooper Report ¶ 273. The cfDNA and the streptavidin beads (still bound together) are discarded, and the ligation product is amplified through universal PCR to form a PCR product, also referred to as an amplification product. Haberny Decl., Ex. 6 at 65:6-17; Haberny Decl., Ex. 3 at 188:14; Corrected Cooper Report ¶¶ 264-265. The amplification products “are then digested [*i.e.*, cleaved or cut up] with restriction endonuclease enzymes,” releasing “Readout Cassettes.” Corrected Cooper Report ¶¶ 273, 285; *see also* Def.’s MSJ at 6; Pls.’ MSJ Opp’n at 5.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁵ Defendant defines “array” as “a collection of DNA fragments attached to microscopic spots on a solid surface. When complementary DNA is applied to the array, it hybridizes with the fragments attached to the array, and therefore become bound to the array.” Def.’s MSJ at 6 n.3.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

[REDACTED]

II. Procedural Background

In October 2012, Verinata and Stanford University sued Ariosa for patent infringement, alleging that the Harmony Test infringed certain claims of the '430 patent and U.S. Patent No. 8,29,076 ("the '076 patent"). *Verinata v. Ariosa*, No. 12-cv-5501 (complaint later amended, *see* Dkt. No. 349).⁷ Ariosa filed counterclaims for declaratory relief of invalidity and non-infringement of the '430 patent. No. 12-cv-5501, Dkt. No. 352. In April 2014, Illumina sued Ariosa, alleging infringement of the '794 patent based on Harmony V1. *Illumina v. Ariosa*, No. 14-cv-1921. In May 2015, Illumina again sued Ariosa for infringement of the '794 patent, but this time based on Harmony V2. *Illumina v. Ariosa*, No. 15-cv-2216.⁸

⁶ [REDACTED]

⁷ LabCorp (a distributor of the Harmony Test) was also named as a defendant in this case, but has since been dismissed pursuant to stipulation. *See* No. 12-cv-5501, Dkt. No. 116. Also by stipulation, Stanford and the claims based on the '076 patent have been dismissed. *See* No. 12-cv-5501, Dkt. No. 347.

⁸ Roche Molecular Systems Inc., which acquired Ariosa around December 2014, was also named as a party in this action. However, pursuant to stipulation, Roche was dismissed from the

Ariosa filed counterclaims against Illumina for declaratory relief of invalidity and non-infringement of the '794 patent, breach of contract, and breach of the covenant of good faith and fair dealing. *See* Third Amended Answer ("TAA"), No. 14-cv-1921, Dkt. No. 102-1 (redacted), Dkt. No. 103-4 (unredacted); Answer to First Amended Complaint, No. 12-cv-5501, Dkt. No., 283. The Court consolidated these three actions. After several stipulations, the parties remaining are plaintiffs Illumina and Verinata, and defendant Ariosa. The remaining patents are the '430 patent and the '794 patent.

LEGAL STANDARD

I. Anti-SLAPP (Cal. Civ. Proc. Code § 425.16)

The California Legislature passed California Civil Procedure Code section 425.16 to address "a disturbing increase" in Strategic Lawsuits Against Public Participation ("SLAPPs"), or suits brought "primarily to chill the valid exercise of the constitutional rights of freedom of speech and petition for the redress of grievances." Cal. Civ. Proc. Code § 425.16(a). Section 425.16 permits counterclaim defendants to bring a "special motion to strike" if a cause of action against them arises "from any act . . . in furtherance of the person's right of petition or free speech . . . in connection with a public issue[.]" *Id.* § 425.16(b)(1), (h). A special motion to strike under section 425.16 is commonly referred to as an anti-SLAPP motion.

In order to prevail on an anti-SLAPP motion, the movant must first make a *prima facie* showing, through the pleadings themselves and supporting affidavits, that the statement or conduct underlying the legal claims against it qualifies for protection under the anti-SLAPP statute. *Id.* § 425.16(b); *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1110 (9th Cir. 2003). The burden then shifts to the non-moving party to demonstrate a probability of prevailing on the challenged claims. Cal. Civ. Proc. Code § 425.16(b)(1); *Vess*, 317 F.3d at 1110. The California Legislature expressly intended that section 425.16 "be construed broadly" in protection of the public interest. Cal. Civ. Proc. Code § 425.16(a). Although it is a state statute, a party may bring an anti-SLAPP

consolidated action, but will be deemed a party to any judgment. *See* No. 12-cv-5501, Dkt. No. 375.

1 motion to strike state law claims in federal court. *Vess*, 317 F.3d at 1109 (citing *United States ex.*
 2 *rel. Newsham v. Lockheed Missiles & Space Co.*, 190 F.3d 963, 970-73 (9th Cir. 1999)).⁹

3 4 **II. Summary Judgment**

5 Summary judgment is proper if the pleadings, the discovery and disclosure materials on
 6 file, and any affidavits show that there is no genuine dispute as to any material fact and that the
 7 movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). The moving party
 8 bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex*
 9 *Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The moving party, however, has no burden to
 10 disprove matters on which the non-moving party will have the burden of proof at trial. The
 11 moving party need only demonstrate to the Court that there is an absence of evidence to support
 12 the non-moving party's case. *Id.* at 325.

13 Once the moving party has met its burden, the burden shifts to the non-moving party to
 14 "designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324 (quoting then
 15 Fed. R. Civ. P. 56(e)). To carry this burden, the non-moving party must "do more than simply
 16 show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co.,*
 17 *Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "The mere existence of a scintilla of
 18 evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find
 19 for the [non-moving party]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

20 In deciding a summary judgment motion, the Court must view the evidence in the light
 21 most favorable to the non-moving party and draw all justifiable inferences in its favor. *Id.* at 255.
 22 "Credibility determinations, the weighing of the evidence, and the drawing of legitimate
 23 inferences from the facts are jury functions, not those of a judge . . . ruling on a motion for
 24 summary judgment" *Id.* However, conclusory, speculative testimony in affidavits and
 25

26
 27 ⁹ The *Newsham* case articulates the current Ninth Circuit law and will be applied here.
 28 However, some judges, including notably Judge Kozinski and Judge Paez of the Ninth Circuit,
 have questioned its correctness. *See, e.g., Makaeff v. Trump University*, 715 F.3d 254 (9th Cir.
 2013) (two separate concurring opinions, each suggesting that the anti-SLAPP statutes are
 procedural, not substantive, and therefore should not be applied in federal courts).

moving papers is insufficient to raise genuine issues of fact and defeat summary judgment. *Thornhill Publ'g Co., Inc. v. Gen. Tel. & Elec. Corp.*, 594 F.2d 730, 738 (9th Cir. 1979). The evidence the parties present must be admissible. Fed. R. Civ. P. 56(c)).

DISCUSSION

I. Defendant's Counterclaims for Breach of Contract and Breach of the Implied Covenant of Good Faith and Fair Dealing

Illumina moves to strike Ariosa's counterclaims for breach of contract and breach of the implied covenant of good faith and fair dealing under California's anti-SLAPP statute, and seek recovery of their attorneys' fees. Pls.' Mot. to Strike ("Pls.' MTS") (Dkt. Nos. 397 (unredacted), 400 (redacted)). In the alternative, Illumina moves for summary judgment on these counterclaims and on Ariosa's license. Pls.'s Mot. for Summary Judgment ("Pls.' MSJ") (Dkt. Nos. 394 (unredacted), 395 (redacted)). Ariosa argues that the California anti-SLAPP statute does not apply to this case and, even if it did, the counterclaims should not be stricken because Ariosa has a probability of prevailing on the merits of those claims. *See* Def.'s Opp'n to Pls.' MTS ("Def.'s MTS Opp'n") (Dkt. Nos. 431 (redacted), 432 (unredacted)); Def.'s Opp'n to Pls.' MSJ ("Def.'s MSJ Opp'n") (Dkt. Nos. 433 (redacted), 435 (unredacted)).

A. Applicability of the Anti-SLAPP Statute

"[A] federal court can only entertain anti-SLAPP special motions to strike in connection with state law claims." *Hilton v. Hallmark Cards*, 599 F.3d 894, 901 (9th Cir. 2010). The anti-SLAPP statute "does not apply to federal causes of action." *Id.* Additionally, "[f]ederal courts have exclusive jurisdiction over cases 'arising under any Act of Congress relating to patents.'" *Gunn v. Minton*, 568 U.S. 251, 253 (2013) (citing 28 U.S.C. § 1338(a)). This applies to two types of cases: (1) cases where federal law creates the cause of action; and (2) a "special small category" of state law claims that "necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 257-58.

1 The parties dispute the applicability of California's anti-SLAPP law to this case.
2 Defendant Ariosa contends that the anti-SLAPP procedure is inapplicable to its counterclaims
3 because they "require the resolution of substantial patent issues," and are, therefore, subject to
4 exclusive federal jurisdiction. Def.'s MTS Opp'n at 6-7. Illumina, on the other hand, argues that
5 the anti-SLAPP statute applies because defendant's counterclaims are governed by California law.
6 Pls.' MTS Reply (Dkt. No. 457-4) at 2-3.

7 In general, the Federal Circuit directs courts to "apply state law to contractual disputes" in
8 patent cases. *Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1320 (Fed. Cir.
9 2017). But "there are certain instances where Federal Circuit law is intimately bound up in the
10 contract interpretation issue." *Id.* at 1320 n.1. For instance, the question of whether an agreement
11 provides for an automatic assignment or simply an obligation to assign a patent is a matter of
12 federal law. *Id.* Here, however, the Court is not persuaded "that this case implicates such
13 exceptions," and the Sale and Supply Agreement specifies that it shall be construed in accordance
14 with California law. *Id.*; Agreement § 32(f). Therefore, the Court finds that the California anti-
15 SLAPP statute is applicable here.

16 17 **B. Anti-SLAPP & Summary Judgment Analysis**

18 In order to prevail on an anti-SLAPP motion, the movant must first make a *prima facie*
19 showing that the conduct underlying the legal claims against it qualifies for protection under the
20 anti-SLAPP statute. Cal. Civ. Proc. Code § 425.16(b); *Vess*, 317 F.3d at 1110. The burden then
21 shifts to the non-moving party to demonstrate a probability of prevailing on the challenged claims.
22 *Id.* Because the analysis under the second prong of the anti-SLAPP statute overlaps with the
23 summary judgment analysis, the Court will address the parties' summary judgment arguments
24 simultaneously. *See Club Members for An Honest Election v. Sierra Club*, 45 Cal.4th 309, 320
25 (Cal. 2008) (finding summary judgment holding was dispositive for determining the second prong
26 of the anti-SLAPP analysis); *see also Roberts v. McAfee, Inc.*, 660 F.3d 1156, 1163 (9th Cir. 2011)
27 (plaintiff's burden to survive an anti-SLAPP motion "resembles the burden he would have in
28 fending off a motion for summary judgment").

1. Protected Activity

Under the first anti-SLAPP prong, the “critical consideration is whether the cause of action is based on the defendant’s protected free speech or petitioning activity.” *Navellier v. Sletten*, 29 Cal. 4th 82, 89 (Cal. 2002) (original emphasis). In making this determination, “a court considers ‘the pleadings, and supporting and opposing affidavits stating the facts upon which the liability or defense is based.’” *Navellier*, 29 Cal. 4th at 89 (quoting § 425.16(b)).

Here, Ariosa’s contract counterclaims are based on Illumina’s filing of the patent infringement action and pre-filing notice of Ariosa’s alleged breach of the parties’ Sale and Supply Agreement. TAA ¶¶ 71-87. A breach of contract claim brought in response to an infringement lawsuit arises from the protected right to petition. *See Powertech Tech., Inc. v. Tessera, Inc.*, 872 F. Supp. 2d 924, 934 (N.D. Cal. 2012). Additionally, “communications preparatory to or in anticipation of the bringing of an action or other official proceeding . . . are equally entitled to the benefits of section 425.16.” *Bailey v. Brewer*, 128 Cal. Rptr. 3d 380, 388 (Ct. App. 2011) (citing *Briggs v. Eden Council for Hope & Opportunity*, 19 Cal. 4th 1106, 1115 (1999)). Thus, the counterclaims arise from a protected activity.

2. Probability of Prevailing & Summary Judgment

The burden now shifts to Ariosa to demonstrate a “reasonable probability that it will prevail” on its counterclaims. *Makaeff*, 715 F.3d at 261. A court should only grant an anti-SLAPP motion when “as a matter of law, [the counterclaim] defendant’s evidence supporting the motion defeats the [counterclaimant’s] attempt to establish evidentiary support for the claim.” *Roberts*, 660 F.3d at 1163. Likewise, summary judgment is proper if there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. *See Fed. R. Civ. P. 56(a)*.

a. Counterclaim for Breach of Contract

The “essential elements” of a breach of contract claim are “(1) the contract, (2) plaintiff’s performance or excuse for nonperformance, (3) defendant’s breach, and (4) the resulting damages

1 to plaintiff.” *Powertech Tech.*, 872 F. Supp. 2d at 934 (quoting *Reichert v. General Ins. Co.*, 68
2 Cal.2d 822, 830 (1968)). The counterclaimant must identify the specific provision breached.
3 *Caraccioli v. Facebook, Inc.*, 167 F. Supp. 3d 1056, 1064 (N.D. Cal. 2016) (citing *Progressive*
4 *West Ins. Co. v. Super. Ct.*, 37 Cal.Rptr.3d 434 (2005)).

5 Illumina moves for summary judgment on the basis that Ariosa cannot show that Illumina
6 breached the parties’ Sale and Supply Agreement. Ariosa asserts that Illumina granted Ariosa an
7 express or implied license to the ’794 patent, and that when Illumina filed its action for patent
8 infringement, it breached the parties’ agreement. The parties dispute whether the filing of a
9 lawsuit can constitute a breach, and whether Illumina granted Ariosa a license to the ’794 patent.

10 Illumina notes that the Sale and Supply Agreement did not contain an express provision
11 prohibiting it from suing Ariosa. Pls.’ MSJ at 14. However, “[a] nonexclusive license is a
12 covenant not to sue[.]” *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1346 (Fed. Cir. 2007); *see*
13 *also Harris v. Emus Records Corp.*, 734 F.2d 1329, 1334 (9th Cir. 1984) (“Under patent law, a
14 license has been characterized as an agreement not to sue the licensee for infringement.”). A
15 covenant not to sue is an agreement not to enforce a cause of action. *Skilstaf, Inc. v. CVS*
16 *Caremark Corp.*, 669 F.3d 1005, 1017 n.10 (9th Cir. 2012). Therefore, the initiation of a lawsuit
17 for infringement despite the existence of a valid license agreement may serve as the basis for a
18 breach of contract claim.

19 The Court now turns to whether Illumina granted Ariosa a license to the ’794 patent. The
20 Agreement provided that the purchase of Goods conferred onto Ariosa “the non-exclusive, non-
21 transferable, personal, non-sublicensable right under Core IP Rights in Goods to use and import
22 (only from Illumina, its Affiliates, or their authorized distributors) the Goods only in the Customer
23 Field of Use.” Agreement § 3(a). “Core IP Rights in Goods” meant “those Illumina Intellectual
24 Property Rights that pertain to the Goods (and use thereof in accordance with their
25 Documentation) other than Secondary Illumina IP Rights in Goods, which are expressly excluded
26 from Core IP Rights in Goods.” *Id.* at 1. “Secondary IP Rights in Goods” was defined as “the
27 secondary Illumina Intellectual Property Rights that pertain to the Goods (and use thereof) only
28

1 with regard to particular field(s) or application(s), and are not common to the Goods in all
2 applications and fields.”

3 There are disputed material facts regarding Ariosa’s claim to an express license, including
4 whether the ’794 patent “pertains” to Ariosa’s use of the Goods and whether the ’794 patent is
5 “Core IP.” Therefore, the Court DENIES Illumina’s summary judgment motion regarding
6 Ariosa’s express license theory of breach. For the same reason, the Court also denies the motion
7 to the extent it sought summary judgment on Ariosa’s license defense. *See* Pls.’ MSJ at 21.

8 However, the same is not true for Ariosa’s alternative theory that if the ’794 patent is
9 Secondary IP, then it had an implied license. “[I]mplied licenses arise by acquiescence, by
10 conduct, by equitable estoppel (estoppel in pais), or by legal estoppel.” *Wang Labs., Inc. v.*
11 *Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997). Ariosa bases its implied
12 license theory on statements made by Illumina representatives before the execution of the Sale and
13 Supply Agreement, and part of Section 4(a) of the Agreement, which states that “[a]s of the
14 Effective Date, and based on information Customer disclosed to Illumina as an investor in
15 Customer, Illumina is not aware that use of the Goods according to their Documentation to
16 perform the Fetal Aneuploidy Service requires a license to any Illumina Secondary IP Rights in
17 Goods.” *See* Def.’s MSJ Opp’n at 19; Agreement § 4(a).

18 However, Section 3(c) expressly disclaims the grant of an implied license, stating that
19 “[n]o right or license under any Illumina Intellectual Property Rights, including without limitation
20 *Secondary IP Rights in Goods*, is or are granted, expressly or *by implication*, to Customer under
21 this Agreement except as expressly stated in Section 3(a).” Agreement § 3(c) (emphasis added).
22 Additionally, the remainder of Section 4 provides:

- 23 a. Customer’s intended use of Goods within the Customer Field of
24 Use during the Term may require that it obtain from third parties
25 or from Illumina (or its Affiliates) additional rights or licenses
26 above the rights conferred in Section 3(a). Customer
27 acknowledges and agrees that it is solely Customer’s
28 responsibility throughout the Term to identify and ensure that it
has all rights from third parties and, with respect to Secondary IP
Rights in Goods, all rights from Illumina that are necessary for
its intended use of Goods in the Customer Field of Use, as it
may be amended pursuant to section (b) . . . If Illumina has
Secondary IP Rights in Goods that Customer requires in order to

1 use the Goods in the Customer Field of Use, then any future
2 grant of such rights will be subject to the Parties' negotiation of
the terms and conditions under which such rights will be
granted, including consideration.

- 3 b. Customer represents, warrants, and covenants that . . . (iii)
4 Customer shall not knowingly use the Goods in any manner that
falls with Secondary IP Rights in Goods without prior express
5 written permission of Illumina provided, if at all, after the
Effective Date.

6 Agreement § 4. Lastly, Section 32(h) mandates that "[t]his Agreement, together with any
7 applicable EULA, represents the entire agreement between the Parties regarding the subject matter
8 hereof and supersedes all prior discussions, communications, agreements, and understandings of
9 any kind and nature between the Parties."

10 The Court agrees with Ariosa that under California law, "[i]t is well settled that a contract
11 should be interpreted to give meaning to each of its provisions." *See Brinderson-Newberg Joint*
12 *Venture v. Pac. Erectors*, 971 F.2d 272, 278-79 (9th Cir. 1992) (applying California law); *see also*
13 Cal. Civ. Code § 1641 ("The whole of a contract is to be taken together, so as to give effect to
14 every part, if reasonably practicable, each clause helping to interpret the other."). The Court
15 disagrees, however, that declining to find an implied license would nullify Illumina's statement
16 that it was not aware that Ariosa needed a license to any Secondary IP. Rather, in light of the
17 express disclaimers listed above, there can be no implied license based on the Agreement or earlier
18 representations by Illumina's representatives. To hold otherwise would nullify those disclaimers.
19 Accordingly, the Court GRANTS summary judgment in favor of Illumina on Ariosa's implied
20 license theory of breach of contract.

21
22 **b. Counterclaim for Breach of the Covenant of Good Faith and**
23 **Fair Dealing**

24 Under California law, every contract "imposes upon each party a duty of good faith and
25 fair dealing in its performance and its enforcement." *McClain v. Octagon Plaza, LLC*, 159 Cal.
26 App. 4th 784, 796 (2008). The elements of a cause of action for breach of the implied covenant of
27 good faith and fair dealing are: "(1) the parties entered into a contract; (2) the plaintiff fulfilled his
28 obligations under the contract; (3) any conditions precedent to the defendant's performance

1 occurred; (4) the defendant unfairly interfered with the plaintiff's rights to receive the benefits of
2 the contract; and (5) the plaintiff was harmed by the defendant's conduct." *Rosenfeld v.*
3 *JPMorgan Chase Bank, N.A.*, 732 F. Supp. 2d 952, 968 (N.D. Cal. 2010) (citing Judicial Council
4 of California Civil Jury Instruction 325).

5 Ariosa claims that Illumina breached the covenant of good faith and fair dealing by filing
6 its patent infringement action against Ariosa "in an attempt to unreasonably deprive [defendant] of
7 the benefits of the Agreement, namely, [defendant's] ability to use the Goods in performing the
8 Harmony™ Prenatal Test." TAA ¶ 85. The claim is also based on Illumina's "pretextual claims
9 of 'breach' of the Agreement by [defendant] in an effort to obtain additional concessions that were
10 foregone during the bargaining process." *Id.* Ariosa alleges that this conduct was done with "the
11 purpose of diminishing [defendant's] ability to compete effectively with 'Verinata,' now a
12 business unit of Illumina, or other competitors." *Id.* It also alleges that this breach deprives
13 Ariosa "of the benefits of the Agreement by disrupting, and impeding [defendant's] relationships
14 with customers, third-party contractors, and investors." *Id.*

15 Illumina argues that Ariosa cannot show that Illumina unfairly interfered with Ariosa's
16 rights to receive the benefits of the Agreement. Pls.'s MSJ at 19. According to Illumina, the only
17 purpose of the Agreement was for Illumina to sell and supply certain materials (which it did). It
18 notes that the Agreement allows a party to notify the other of a breach and does not contain an
19 express covenant not to sue. *Id.* It also contends that "[w]ithout specific prohibitions in the
20 Agreement precluding such conduct, the filing of a patent infringement action cannot be a proper
21 ground for [defendant's] breach of good faith and fair dealing claim." *Id.*

22 "[B]reach of a specific provision of the contract is not a necessary prerequisite" to a claim
23 for breach of the covenant of good faith and fair dealing. *Carma Developers (Cal.), Inc. v.*
24 *Marathon Dev. California, Inc.*, 2 Cal. 4th 342, 373 (1992). But "the scope of conduct prohibited
25 by the covenant of good faith is circumscribed by the purposes and express terms of the contract."
26 *Id.* The California Supreme Court has recognized that a difficulty may arise when determining
27 whether certain conduct, "though not prohibited, is nevertheless contrary to the contract's
28 purposes and the parties' legitimate expectations." *Id.*

As discussed above, a license is a covenant not to sue. If Ariosa establishes that it had a license to the '794 patent under the Agreement, then the filing of the patent infringement lawsuit may constitute a breach. Additionally, Illumina's view of the benefits promised to Ariosa under the bargain is too narrow. Rather, the Agreement explicitly contemplated Ariosa's ability to use the goods supplied by Illumina. *See, e.g.*, Agreement §§ 2(b), 3(a). Thus, Ariosa may argue that Illumina interfered with Ariosa's right to use the goods within the Customer Field of Use to support its breach of covenant claim. Whether Illumina did so is for the jury.

c. Damages from the Contract Counterclaims

The parties also dispute whether Ariosa can establish damages from the alleged breach, which is an essential element of Ariosa's contract counterclaims. *See Bramalea California, Inc. v. Reliable Interiors, Inc.*, 119 Cal. App.4th 468, 473 (2004) ("A breach of contract is not actionable without damage."); *Rosenfeld*, 732 F. Supp. 2d at 968. Ariosa alleges that it suffered damages, including expenses associated with its withdrawn IPO and lost business value, such as loss of proceeds from the IPO and opportunity costs. TAA ¶ 76; *see also* Haberny Decl., Ex. 53 (Ariosa's damages expert report). For instance, it alleges that but for the infringement action, "it would have been able to implement its planned expansion of its commercial operations and thereby increase sales, revenues, and profits." TAA ¶ 76. It also alleges that it had to "expend resources to attempt to replace the lost proceeds and restore market, investor, and partner confidence in [defendant]." *Id.* Ariosa also alleges damages "in the form of costs associated with transitioning from the Illumina platform, *i.e.*, the sequencing equipment and chemical reagents on which the Harmony™ Prenatal Test currently operates, to an alternative platform[.]" *Id.* ¶ 77. It contends that it had to "accelerate alternative options," which required "significant time and money." Additionally, Ariosa asserts damages based on lost sales, revenue, and profits. *Id.* ¶ 78.

Illumina argues that Ariosa cannot show that Illumina caused the alleged damages. Pls.' MTS at 11; Pls.' MSJ at 17. But there are factual disputes regarding causation, including whether Ariosa postponed or canceled its IPO before Illumina filed its infringement action, whether Ariosa's inability to find other distribution partners was caused by the lawsuit, and whether Ariosa

1 accelerated its transition to a microarray platform because of the lawsuit. *Compare* Pls.’ MTS at
 2 11, Pls.’ MSJ at 17 *with* Haberny Decl., Ex. 53 (Ariosa’s damages expert report). Therefore,
 3 summary judgment is not appropriate on this ground.

4 Illumina next argues that even if causation is established, Ariosa’s alleged damages are
 5 barred by the Sale and Supply Agreement’s limitation of liability clause. Ariosa responds that if
 6 the clause is interpreted to bar all recovery for a “willful” breach, it is unenforceable. The
 7 relevant clause states:

8 **Limitation of Liability.** TO THE EXTENT PERMITTED BY
 9 LAW, IN NO EVENT SHALL ILLUMINA OR ITS SUPPLIERS,
 10 OR CUSTOMER, BE LIABLE TO EACH OTHER OR ANY
 11 THIRD PARTY FOR COSTS OF PROCUREMENT OF
 12 SUBSTITUTE PRODUCTS OR SERVICES, LOST PROFITS,
 13 DATA OR BUSINESS, OR FOR ANY INDIRECT, SPECIAL,
 14 INCIDENTAL, EXEMPLARY, CONSEQUENTIAL, OR
 15 PUNITIVE DAMAGES OF ANY KIND ARISING OUT OF OR IN
 16 CONNECTION WITH THIS AGREEMENT, HOWEVER
 17 CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER
 18 IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT
 LIABILITY OR OTHERWISE). ILLUMINA'S TOTAL AND
 CUMULATIVE LIABILITY ARISING UNDER OR IN
 CONNECTION WITH THIS AGREEMENT, WHETHER IN
 CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT
 LIABILITY OR OTHERWISE SHALL IN NO EVENT EXCEED
 THE AMOUNT RECEIVED BY ILLUMINA FROM CUSTOMER
 UNDER THIS AGREEMENT. THE LIMITATIONS SET FORTH
 IN THIS SECTION 18 SHALL APPLY EVEN IF A PARTY HAS
 BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES,
 AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL
 PURPOSE OF ANY LIMITED REMEDY.

19 Agreement § 18 (original emphasis).

20 Limitation of liability clauses “have long been recognized as valid in California.” *Food*
 21 *Safety Net Servs. v. Eco Safe Sys. USA, Inc.*, 209 Cal. App. 4th 1118, 1126 (2012). “With respect
 22 to claims for breach of contract, limitation of liability clauses are enforceable unless they are
 23 unconscionable, that is, the improper result of unequal bargaining power or contrary to public
 24 policy.” *Id.*; *see also* Cal. Civ. Code § 1668 (“All contracts which have for their object, directly or
 25 indirectly, to exempt anyone from responsibility for his own . . . willful injury to the person or
 26 property of another . . . are against the policy of the law.”).

27 Section 18 does not prohibit all of Ariosa’s damages. At the very least, it allows Ariosa to
 28 recover direct damages up to the amount that Ariosa paid to Illumina under the agreement. Also,

because Ariosa has argued there is evidence showing that Illumina willfully injured Ariosa's business after it acquired Verinata and became a competitor, there is a factual dispute underlying whether the limitation of liability provision is enforceable. *See* Def.'s MSJ Opp'n at 23. *Civic Ctr. Drive Apartments Ltd. Partn. v. S.W. Bell Video Servs.*, 295 F. Supp. 2d 1091, 1105 (N.D. Cal. 2003) (Spero, J.) (denying summary judgment where enforceability of limitation of liability clause turned on disputed facts); *cf. Darnaa, LLC v. Google Inc.*, 236 F. Supp. 3d 1116, 1125 (N.D. Cal. 2017) (Alsup, J.) (finding clause enforceable where plaintiff stated a claim for breach of the covenant of good faith and fair dealing, but did not allege that defendant willfully or intentionally injured plaintiff's property). Accordingly, summary judgment is inappropriate on this ground.

In sum, the Court GRANTS summary judgment in favor of Illumina on Ariosa's implied license theory of breach of contract, and DENIES the motion in regards to the express license theory of breach of contract claim and the breach of covenant of good faith and fair dealing claim.¹⁰

II. Patent Validity & Assignor Estoppel

Plaintiffs also move for summary judgment on Ariosa's declaratory relief counterclaim to the extent it seeks a declaration of invalidity of the '794 patent. Plaintiffs argue that this counterclaim is barred by the doctrine of assignor estoppel because two of Ariosa's founders—John Stuelpnagel and Arnold Oliphant—are in privity with Ariosa, are named inventors of the '794 patent, and assigned to Illumina rights in the patent application from which the '794 patent ultimately issued. In response, Ariosa argues that Stuelpnagel and Oliphant's invention is not claimed in the '794 patent and that the equities weigh against estoppel.

"Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity. The estoppel also operates to bar other parties in privity with the assignor, such as a corporation

¹⁰ Because both contract counterclaims survive, plaintiffs' request for fees for its anti-SLAPP motion is DENIED.

1 founded by the assignor.” *Diamond Sci. Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224 (Fed. Cir.
2 1988). “This doctrine prevents the ‘unfairness and injustice’ of permitting a party ‘to sell
3 something and later to assert that what was sold is worthless.’” *Mentor Graphics Corp. v.*
4 *Quickturn Design Sys., Inc.*, 150 F.3d 1374, 1377 (Fed. Cir. 1998). “A determination whether
5 assignor estoppel applies in a particular case requires a balancing of the equities between the
6 parties.” *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1579 (Fed. Cir. 1993).
7 The determination of whether to apply the doctrine of assignor estoppel is “committed to the
8 sound discretion of the trial court.” *Id.*

9 It is undisputed that Ariosa is in privity with Stuelpnagel and Oliphant. *See* Hearing
10 Transcript (Dkt. Nos. 486, 487) at 50:16. But the question remains, and the parties greatly
11 dispute, whether Stuelpnagel and Oliphant assigned to Illumina an invention that is claimed in the
12 ’794 patent. The issue turns on whether the invention assigned by Stuelpnagel and Oliphant to
13 Illumina is different from or merely a narrower version of the invention claimed in the ’794 patent.
14 Although assignor estoppel is an equitable doctrine for the Court to ultimately decide, these
15 subsidiary factual disputes make summary judgment on the issue inappropriate at this time.
16 Therefore, the Court DENIES plaintiffs’ motion for summary judgment on the issue of assignor
17 estoppel.

18 19 **III. Motions to Strike and Preclude Plaintiffs’ Expert Dr. Cooper’s Report & Related** 20 **Testimony**

21 Dr. Gregory Cooper is plaintiffs’ technical expert. Ariosa filed two motions attacking the
22 Corrected Expert Report of Gregory Cooper, Ph.D., and related testimony from his July 26, 2017
23 deposition. The first moves to strike portions of the report and testimony on the ground that they
24 contain new and untimely infringement theories. Def.’s Motion to Strike (“Def.’s MTS”) (Dkt.
25 Nos. 399-4 (unredacted), 442 (redacted)). The second presents a *Daubert* challenge to a separate
26 portion of the report. Def.’s Mot. to Preclude Cooper (Dkt. No. 401).

A. Motion to Strike

Ariosa argues that plaintiffs are relying on several theories of infringement that were not identified in their September 30, 2016 Patent Local Rule infringement contentions, and were instead disclosed for the first time in Dr. Cooper's report served June 2, 2017 (corrected June 27, 2017) and his July 26, 2017 deposition testimony. Patent Local Rule 3-1 requires a patent infringement plaintiff to serve a "Disclosure of Asserted Claims and Infringement Contentions," which must include "[e]ach claim of each patent in suit that is allegedly infringed by each opposing party, including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted." Patent L.R. 3-1(a). The plaintiff must also identify "specifically where and how each limitation of each asserted claim is found within each Accused Instrumentality," and "[w]hether each limitation of each asserted claim is alleged to be literally present or present under the doctrine of equivalents." Patent L.R. 3-1(c), (e). "[A]ll courts agree that the degree of specificity under Local Rule 3-1 must be sufficient to provide reasonable notice to the defendant why the plaintiff believes it has a 'reasonable chance of proving infringement.'" *Shared Memory Graphics LLC v. Apple, Inc.*, 812 F. Supp. 2d 1022, 1025 (N.D. Cal. 2010) (quoting *View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000)). But "[p]arties . . . need not 'prove up' their theories by providing evidence beyond the material they have at the time they make their contentions." *Apple Inc. v. Samsung Electronics Co.*, No. 12-cv-0630-LHK PSG, 2013 WL 3246094, at *3 (N.D. Cal. June 26, 2013).

The Northern District of California's Patent Local Rules "exist to further the goal of full and timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l*, No. C 03-1431 SBA, 2006 U.S. Dist. LEXIS 90856, at *12 (N.D. Cal. May 15, 2006). "The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Id.*; accord *O2 Micro Int'l, Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) ("The rules . . . seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories."). District courts have "wide discretion" in enforcing the Patent Local Rules. *Finjan, Inc. v. Proofpoint, Inc.*, No.

13-cv-5808-HSG, 2015 WL 9460295, at *1 (N.D. Cal. Dec. 23, 2015) (citing *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1292 (Fed. Cir. 2005)).

“Given the purpose behind the patent local rules’ disclosure requirements, ‘a party may not use an expert report to introduce new infringement theories, new infringing instrumentalities, new invalidity theories, or new prior art references not disclosed in the parties’ infringement contentions or invalidity contentions.’” *Verinata Health, Inc. v. Sequenom, Inc.*, No. C 12-00865 SI, 2014 WL 4100638, at *3 (N.D. Cal. Aug. 20, 2014) (internal citations omitted). However, the “scope of contentions and expert reports are not . . . coextensive.” *Golden Bridge Tech. Inc. v. Apple, Inc.*, No. 12-cv-4882-PSG, 2014 WL 1928977, at *3 (N.D. Cal. 2014) (internal quotation marks omitted). “Contentions need not disclose specific evidence, whereas expert reports must include a complete statement of the expert’s opinions, the basis and reasons for them, and any data or other information considered when forming them.” *Id.* “The dispositive inquiry in a motion to strike is thus whether the allegedly undisclosed ‘theory’ is in fact a new theory or new element of the accused product alleged to practice a particular claim that was not previously identified in the plaintiff’s contentions, or whether the ‘theory’ is instead the identification of additional evidentiary proof showing that the accused element did in fact practice the limitation.” *Finjan, Inc. v. Blue Coat Sys., Inc.*, No. 13-cv-3999-BLF, 2015 WL 3640694, at *2 (N.D. Cal. June 11, 2015). “If the theory is *new*, prejudice is ‘inherent in the assertion of a new theory after discovery has closed.’” *Id.* (original emphasis).

1. Literal Infringement Theory for Step (a)

Claim 1, step (a) requires “providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support.” Ariosa seeks to strike paragraph 90 of the Corrected Cooper Report and related deposition testimony as introducing a new literal infringement theory for step (a). To meet step (a), Illumina’s infringement contentions included the reference to: “Cell-free DNA (cfDNA) (black) is first labeled with biotin (B) moiety and bound to streptavidin-coated magnetic beads (SA).” Haberny Decl., Ex. 13, Appendix A at 4. This is the same element that Dr. Cooper’s report identifies as infringing: single-stranded cfDNA

(the alleged “single-stranded target sequences”) are attached to streptavidin beads (the alleged “first solid support”). The Corrected Cooper Report does not contain a new element accused of infringing the patent-in-suit.

Ariosa, however, reads Illumina’s infringement contentions as disclosing a theory that step (a) is met only if the single-stranded cfDNA is bound to streptavidin beads before the sample is provided into the method. But nothing in the infringement contentions limits Illumina’s infringement theory in this manner. Rather, Ariosa’s argument is based on its own claim construction view that the target sequences must already be attached to a first solid support before the sample is provided. In light of that view, Ariosa asserts that any theory allowing the attachment to occur during step (a) or at any other time is new. Def.’s MTS at 5-6. In contrast, Illumina asserts that the claim language does not require such a construction. The Court DENIES the motion to strike on this basis, and reaches the merits of the parties’ respective claim construction positions in the summary judgment discussion below.

2. The Order of Steps

Ariosa next asks the Court to strike paragraphs 79, 90-94, 223, 235-239, and the introductory lines of paragraphs 95 and 240 from the Corrected Cooper Report, as well as related deposition testimony. Def.’s MTS at 7. Ariosa argues that this testimony asserts that step (a) is literally infringed even if steps (b) and (d) are performed first.

The Court previously denied Illumina’s motion for leave to amend its infringement contentions. February 14, 2017 Order (Dkt. No. 329). The following is the proposed doctrine of equivalents theory regarding step 1(a) that the Court did not allow:

Likewise, to the extent Ariosa contends that this claim element is not satisfied because Ariosa attaches double-stranded hybridization complexes to a solid support rather than single-stranded target sequences, any such difference between these two approaches is insubstantial. The only difference between these two approaches is the order in which the probe set is added to the reaction mix. Otherwise, the two approaches are performed identically and there is thus no substantial difference between the two techniques. *Whether the probes are added before or after biotinylated single target sequences are attached to streptavidin beads has no impact on the*

performance, efficiencies, kinetics, or systems engineering of the claimed method, further showing that the two approaches are thus equivalent. Further, even where probes are added before single target sequences are attached to streptavidin beads, the single stranded target sequences are still ultimately attached to a solid support, albeit while hybridized to probes. As such, there is no substantial difference between the two approaches, and the two approaches lead to the same result.

Dkt. No. 310-8 at 7 (emphasis added). Although Illumina characterizes the theory contained in Dr. Cooper's report as a literal infringement theory, it is substantively no different than the doctrine of equivalents theory that the court disallowed. *See* Pls.' MTS Opp'n at 8; *compare* Dkt. No. 310-8 at 7 with Corrected Cooper Report ¶¶ 90, 236.

However, the parties dispute whether the claim language recites a necessary order for steps (a) and (b). Ariosa argues that steps (a) and (b) must be performed in that order; Illumina argues that the order in which they are performed does not matter; and they each argue that the other has waived its respective position. Illumina contends (and Ariosa disputes) that Ariosa took a contrary position during IPR proceedings. Illumina points to a portion of its IPR brief stating that step (a) can occur before or after step (b), and Ariosa's IPR brief that argued in a footnote that the '794 patent was anticipated by an earlier patent application based on Illumina's argument that steps (a) and (b) need not be performed in order. Opp'n to Def.'s MTS at 6; Walter Decl. ISO Opp'n to Def.'s MTS (Dkt. No. 439), Ex. 7 at 14, Ex. 8 at 6 n.3. Illumina also notes that Ariosa's witness in the IPR testified that one could practice claim 1 by performing step (b) before step (a). *Id.* at 5-6; *see also* Walter Decl. ISO Opp'n to Def.'s MTS, Ex. 6 at 163:23 – 164:4. Ariosa, on the other hand, cites to portions of its and parent company Roche's IPR submissions, as well as expert declarations, asserting that the '794 patent requires the steps to be performed in the order written. *See* Def.'s MTS Reply (Dkt. Nos. 447-4 (unredacted), 448 (redacted)) at 7-8.

Illumina further notes that in Ariosa's September 2004 Patent Local Rule 4-2 Disclosures, Ariosa stated that the "asserted method claims of the '794 patent require performance of the recited steps in the order recited." Haberny Decl., Ex. 15 at 3. But Ariosa never raised this issue during claim construction. On the other hand, Ariosa states that it ultimately decided not to raise the issue in the interest of judicial efficiency because Illumina never argued that the steps could be performed in a different order. Def.'s MTS at 8-9.

All of this finger pointing leads the Court to one conclusion: both parties were sufficiently aware of the order-of-steps issue and should have raised it much earlier. Nonetheless, the Court finds it more appropriate to reach the merits of the parties' claim construction arguments contained in the summary judgment briefing, rather than to decide the issue on a motion to strike. Therefore, the motion to strike on the order of steps issue is DENIED.

3. **Literal Infringement Theory that Readout Cassettes are "Amplicons" as Recited in Steps (f) and (g)**

Step (f) recites: "immobilizing said different amplicons to a second solid support." Step (g) recites: "detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences." Ariosa asks the Court to strike paragraphs 273-276, 283-287, and 298 of the Corrected Cooper Report and related deposition testimony as containing new literal infringement theories regarding steps (f) and (g). Def.'s MTS at 9. These paragraphs claim that Harmony V2's "Readout Cassettes"—which are created after the amplification products are digested or cleaved—literally are "amplicons."

Ariosa argues that "Illumina's infringement contentions as to Harmony V2 do *not* allege that the immobilization of Readout Cassettes, as produced after digestion of amplification products and applied to the alleged second solid support, *literally* satisfies steps 1(f) or 1(g)." Def.'s MTS at 9 (original emphasis). The Court agrees. Illumina's infringement contentions only presented this issue as a doctrine of equivalents theory. *See* Haberny Decl., Ex. 13, Appendix A at 13 ("To the extent that Ariosa contends its process does not meet the literal terms of the claims because it only immobilizes a portion of the amplicon [REDACTED]

[REDACTED] the difference is insubstantial [REDACTED]
[REDACTED]

Illumina's argument that it presented this as a literal infringement theory is unpersuasive. First, it notes that its infringement contentions cite to one of Ariosa's earlier patent applications, which stated: "[a] portion of the ligation assay product produced from each sample was amplified using universal primers and sequenced and the remaining portion of the ligation assay product was

hybridized to a custom manufactured DNA array.” Haberny Decl., Ex. 13, Appendix A at 13. However, as Ariosa points out, Illumina omitted from its literal infringement theory the very next sentence of that reference, which states: “Prior to hybridization, the amplicons were cleaved.” Def.’s MTS Reply at 10; Haberny Decl., Ex. 13, Appendix A at Ex. 1 ¶ [0196]. Illumina also points to its complaint, which identified cleaved amplicons hybridized to the microarray. *See* Case No. 15-cv-2216, Dkt. No. 17, ¶¶ 20-21. But this only demonstrates that Illumina knew of the alleged infringing feature and chose to include it only as a doctrine of equivalents theory. *See* Patent L.R. 3-1(b) (identification of the accused instrumentality “shall be as specific as possible”). Therefore, the Court GRANTS the motion to strike the theory that Readout Cassettes are literally “amplicons.” However, to the extent Illumina relies on the above listed paragraphs and deposition testimony to support its doctrine of equivalents theory, it may continue to do so.

4. Theory that Detecting [REDACTED] Satisfies Claim 1’s Preamble and Step (g)

Claim 1’s preamble states: “A multiplex method for determining whether a sample contains at least 100 different target sequences[.]” Step (g) recites: “detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences.” Ariosa seeks to strike paragraphs 191-193, 195-197, 204-207, 208-210, 283, 285-289, and 293-296 of the Corrected Cooper Report, as well as related deposition testimony. Def.’s MTS at 10. It asserts that these paragraphs identify for the first time [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1 However, Illumina’s infringement contentions identified the custom Affymetrix array that
2 contains these features, [REDACTED]
3 [REDACTED]
4 [REDACTED] Illumina acknowledges that the Corrected
5 Cooper Report contains additional details regarding how the microarray operates, but asserts that it
6 could not have provided such detail at the time it served its infringement contentions. Pls.’ MTS
7 Opp’n at 12. Accordingly, Illumina’s contentions reasonably placed Ariosa on notice [REDACTED]
8 [REDACTED]
9 “While greater specificity is certainly preferable, the Patent Local Rules do not require perfect
10 clarity, only reasonable notice that is ‘as specific as possible’ given the information of which the
11 plaintiff is aware.” *Finjan*, 2015 WL 3640694, at *3. Therefore, Ariosa’s motion to strike
12 plaintiff’s evidence of infringement [REDACTED]
13 is DENIED.

14
15 **5.** [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED]
28 [REDACTED]

B. Motion to Preclude the Testimony of Gregory Cooper, Ph.D.

Ariosa further moves to preclude Dr. Cooper from offering the opinion set forth in paragraphs 240 – 244 of his corrected expert report and in related deposition testimony. Dkt. No. 401. This testimony argues that even if step 1(a) must be performed before step 1(b), Harmony V2 still infringes the '794 patent. In particular, Dr. Cooper opines:

[E]ven if one posits that the order of steps (a) and (b) of Claim 1 is essential to the methodological definition of claim 1, at least 100 of the target sequences would almost certainly exist in the single-stranded form even after the oligonucleotide probes are allowed to anneal to the target sequences for 2 hours, and only become bound to oligonucleotide probes after mixing with and attaching to SA beads. This is a result of the sheer numbers of fragments and target sequences involved, the complexity of the solution in which target sequences and probes are mixed, and reaction dynamics.

Corrected Cooper Report ¶ 240. The report bases this conclusion on, *inter alia*, the amount of cfDNA used in Harmony V2, the temperature applied, the mass of a DNA nucleotide, the number of target sequences and their approximate length, and other witness testimony. *See id.* ¶¶ 240-244. Ariosa argues that this testimony is speculative and unreliable, failing the requirements of Federal Rule of Evidence 702. *Id.*

The trial court is vested with the authority to make a “preliminary assessment of whether reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology can properly be applied to the facts in issue.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993), “The district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would

1 be helpful to a jury.” *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969-70 (9th
2 Cir. 2013). When assessing the reliability component of an expert’s testimony, courts are
3 encouraged to examine “(1) whether the theory can be and has been tested; (2) whether it has been
4 subjected to peer review and publication; (3) the known or potential error rate; and (4) whether the
5 theory or methodology employed is generally accepted in the relevant scientific community.”
6 *Daubert*, 509 U.S. at 593-594. “The ‘list of factors was meant to be helpful, not definitive,’ and
7 the trial court has discretion to decide how to test an expert’s reliability as well as whether the
8 testimony is reliable, based on the ‘particular circumstances of the particular case.’” *Primiano v.*
9 *Cook*, 598 F.3d 558, 564 (9th Cir. 2010). “Shaky but admissible evidence is to be attacked by
10 cross examination, contrary evidence, and attention to the burden of proof, not exclusion.” *Id.*

11 After reviewing the disputed paragraphs in the Corrected Cooper Report, Dr. Cooper’s
12 deposition transcript, and Dr. Cooper’s declaration, the Court concludes that Ariosa’s arguments
13 go to the weight rather than admissibility of the testimony. *See* Corrected Cooper Report ¶¶ 240-
14 244; Cooper Decl. ¶¶ 22-30 (describing basis for the disputed opinion). Therefore, the request to
15 preclude this portion of Dr. Cooper’s testimony is DENIED.

16 17 **IV. Patent Infringement**

18 Ariosa moves for summary judgment that neither Harmony V1 nor Harmony V2 infringes
19 the ’794 patent. In particular, it asserts that neither version of the Harmony test satisfies step (a) of
20 Claim 1, and that Harmony V2 also does not satisfy steps (b), (f), or (g). “Summary judgment on
21 the issue of infringement [or noninfringement] is proper when no reasonable jury could find that
22 every limitation recited in a properly construed claim either is or is not found in the accused
23 device either literally or under the doctrine of equivalents.” *PC Connector Solution LLC v.*
24 *SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005).

A. Claim Construction

As a preliminary issue, the parties offer competing claim constructions regarding whether the steps of Claim 1 must be performed in the order written. Claim construction is a matter of law. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 372 (1996). “As a general rule, ‘[u]nless the steps of a method [claim] actually recite an order, the steps are not ordinarily construed to require one.’” *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398 (Fed. Cir. 2014) (quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed.Cir. 2001)); see also *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1345 (Fed. Cir. 2008) (“[A]lthough a method claim necessarily recites the steps of the method in a particular order, as a general rule the claim is not limited to performance of the steps in the order recited, unless the claim explicitly or implicitly requires a specific order.”). “However, a claim ‘requires an ordering of steps when the claim language, as a matter of logic or grammar requires that the steps be performed in the order written, or the specification directly or implicitly requires’ an order of steps.” *Mformation Techs.*, 764 F.3d at 1398; see also *Altris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369-70 (Fed. Cir. 2003) (courts look first to grammar and logic, and then to the specification and prosecution history). “If the claim language is clear on its face, then [the Court’s] consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified.” *Interactive Gift*, 256 F.3d at 1331.

Here, the relevant language of Claim 1 states:

A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising:

a) providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;

b) contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises:

i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and

ii) a target specific domain, such that different double-stranded hybridization complexes are formed, each of the different

hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample;

...

d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes[.]

The '794 Patent at 68:46-67.

1. "Attached" in Step (a)

The parties disagree whether single-stranded target sequences must be attached to a first solid support before "providing" the sample, or if the attachment can occur during step (a). Ariosa argues that the word "attached" is a past participle, requiring the target sequences to be attached to the first solid support before the sample is provided. Def.'s MSJ at 10. Ariosa also points to the prosecution history. Claim 1 originally recited "a) providing a first solid support comprising at least a first and second target sequence." Haberny Decl., Ex. 9 at 84. Ariosa argues that this "language indicates that the target sequences are in fact *part of* the solid support that is provided at the start of the method." Def.'s MSJ at 12. The examiner later amended the language to: "a) providing [a first solid support comprising] a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support." Haberny Decl., Ex. 10 at 3 (brackets indicate deleted language; underlining indicates added language). The examiner's rationale for the amendment was "to clarify particular wording of the claims, and does not change the scope of the claims." *Id.* at 6. Because neither version of the Harmony Test provides a sample with single-stranded cfDNA already immobilized or attached to streptavidin beads (the alleged "first solid support"), Ariosa argues that the tests cannot meet step (a). Def.'s MSJ Reply at 1.

The Court finds Ariosa's argument unpersuasive. "It is settled Federal Circuit law that when a past participle used in one step of a method claim references an action that occurred in a previous step, those steps must be performed in the order written." *N5 Techs. LLC v. Capital One N.A.*, 22 F. Supp. 3d 572, 582-83 (E.D. Va. 2013) (citing *Tuna Processors, Inc. v. Hawaii Intern. Seafood, Inc.*, 327 Fed. Appx. 204, 209 (Fed. Cir. 2009)). Here, however, "attached" does not refer to any other step in the claim where the attachment would have occurred. Additionally,

1 Illumina presented evidence that “one of ordinary skill in the art would understand that step (a)
2 includes an attachment step.” Declaration of Gregory Cooper, Ph.D. (Dkt. Nos. 467-1
3 (unredacted), 475-1 (redacted)) ¶ 9; *see also id.* ¶ 20. This view is supported by Ariosa’s expert’s
4 testimony that the claim “requires the use of two immobilization steps,” including an
5 “immobilization step prior to any biochemistry.” Walter Decl. ISO Opp’n to MSJ, Ex. 4 at 37:15-
6 20. Therefore, “attachment” of the single-stranded target sequences to a first solid support can
7 occur during step (a).

8 9 **2. Order of Steps (a), (b), and (d)**

10 The parties also dispute whether Claim 1 requires step (a) to be performed before step (b)
11 and step (d). There appears to be no dispute that step (d) must be performed after step (b).¹¹
12 Therefore, the Court focuses its analysis on whether steps (a) and (b) must be performed
13 sequentially.

14 Illumina argues that the claim does not require an order of steps because nothing in step (a)
15 specifies when the “providing” needs to happen. Pls.’s MSJ Opp’n at 10. It further contends that
16 because step (b) does not use a past participle before “target sequences” to refer to step (a), no
17 order of steps is imposed. *Id.* Illumina also asserts that “said target sequences” in step (b) refers
18 to the preamble, rather than the intervening step (a), because the term “target sequences” appears
19 first in the preamble.

20 These arguments are unconvincing. The Court recognizes that “in a method claim, a step
21 that recites ‘said’ or ‘the,’ referring to an earlier object, does not always have to be performed after
22 the step that first introduces the object.” *Respironics, Inc. v. Invacare Corp.*, 303 F. App’x 865,
23 870 (Fed. Cir. 2008). But in this instance, read as a whole, the Court finds that the grammar and
24 logic of the claim implies that step (b) cannot be performed before step (a). Step (a) provides a
25 sample into the method. In step (b), hybridization complexes are formed, comprising *inter alia*
26

27
28 ¹¹ Step (d) involves “contacting said probes of the hybridization complexes with a first
enzyme and forming different modified probes.” Because the hybridization complexes cannot be
contacted before they are formed, step (b) must precede step (d).

“one of the different single-stranded target sequences *from the sample*.” Forming such a hybridization complex cannot occur until the sample has been provided. *See* Walter Decl. ISO Pls.’ MSJ Opp’n, Ex. 4 (Cantor Transcript) at 249:9-14 (“because of the word ‘providing,’ I don’t think it leaves you with any flexibility in terms of the order of steps. If you tried to reverse the order, it doesn’t operate.”). Step (b) also involves contacting “said target sequences,” in reference to step (a).

Experts on both sides have opined that there is no meaningful difference in outcome between first adding the probes to form hybridization complexes with the target sequences or first attaching the target sequences to a solid support. *See, e.g.,* Walter Decl. ISO Opp’n to Def.’s MSJ, Ex. 4 at 78:10-13 (Dr. Cantor testifying that “frankly, in my opinion, it doesn’t matter that much whether you immobilize and then hybridize or hybridize and then immobilize); Cooper Report ¶¶ 90, 236. But whether it is possible to have a system that allows for formation of hybridization complexes before immobilization (also referred to as “hybridization in solution”) is not the relevant question. Rather, the Court must determine what the claim language, as written, requires. Focusing on whether hybridization or immobilization can occur in different orders ignores the part of step (a) that requires providing a sample of target sequences that are used to form the hybridization complexes in step (b). Therefore, the Court finds that the grammar and logic—“at least in the absence of compelling evidence to the contrary in the written description or prosecution history”—dictate that step (b) cannot be performed before step (a). *Combined Sys. v. Def. Tech. Corp. of Am.*, 350 F.3d 1207, 1211 (Fed. Cir. 2003).

The Court now turns to the specification, which Illumina contends shows that the claim steps can be performed in any order. Because the claim language is “clear on its face,” the Court’s “consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified.” *Interactive Gift*, 256 F.3d at 1331.

The specification provides:

In general, the method includes a complexity reduction component, a specificity step and an amplification step

[E]ach of the three components can be performed in any order. One of skill in the art will appreciate that when amplification is performed first, there will likely be some degree of complexity

reduction or specificity involved. In addition, when specificity components are performed first, there will be a degree of complexity reduction. In addition, in some embodiments when amplification is first performed, there will be some degree of specificity and complexity reduction.

The '794 Patent at 5:47-48, 9:22-28. The parties dispute which steps of claim 1 make up each of the three components. Ariosa contends that Illumina represented during its tutorial that steps (a) through (c) are the complexity reduction component, step (d) is the specificity component, and step (e) is the amplification component. Def.'s MSJ Reply at 9; Haberny Decl., Ex. 72. Illumina argues that the components are overlapping and that step (b) is also part of the specificity component. *See* Hearing Tr. 82:10-17. In any event, the specification implies that regardless of which component is performed first, there will likely be some degree of complexity reduction done in the beginning. Because step (a) is part of the complexity reduction component, the Court is not persuaded that this passage from the specification requires deviation from the clear claim language.

The specification also states that "the reactions outlined herein may be accomplished in a variety of ways Components of the reaction may be added simultaneously, or sequentially, in any order[.]" *Id.* at 6:24-28. The specification further provides that "[i]n a preferred embodiment complexity reduction is accomplished by selectively immobilizing a primer that has been modified in a target specific manner. That is, either locus specific or allele specific primers are hybridized with a target. The target can be immobilized or in solution." *Id.* at 14:32-36. Ariosa argues that this is boilerplate language that should be rejected, and that any solution-based form "describes an unclaimed embodiment that was expressly disclaimed during prosecution." Def.'s MSJ Reply at 9.

Based on the prosecution history, Ariosa asserts that "[t]he doctrine of prosecution disclaimer bars plaintiff from arguing that the order of the steps in Claim 1 may be reversed." Def.'s MSJ at 14 (citing *N5 Techs.*, 22 F. Supp. 3d at 584). "[W]hen the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim

surrendered.” *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013).
 “Such statements can take the form of either amendment or argument.” *Id.*

Ariosa argues that in order to avoid a rejection for indefiniteness, Illumina represented to the USPTO during prosecution that step (b) referred back to step (a). The following is the representative passage:

[T]he Office asserts that claim 1 is vague and indefinite in view of the phrase “if a target specific domain of a probe is substantially complementary to at least a portion of an individual target sequence” in ii) of step b) because it is allegedly unclear that a probe in the phrase is a probe from the probe set or not and an individual target sequence in the phrase is from the different single-stranded sequences or not. Applicants respectfully advise the Office that yes, the probe in step (b) is “from the probe set” in step (b) and *an individual target sequence in step (b)(ii) is from the different single-stranded target sequences in step (a) . . . [T]he skilled artisan would understand that “an individual” target sequence is from among the earlier-mentioned ‘different’ target sequences.*

Haberny Decl., Ex. 11 at 7 (italic emphasis added; underline in original).

Illumina’s expert argues that this language is not a disclaimer. In support of this position, he opines that “[t]his was simply a clarification that there is a relationship between the probes and target sequences in step (a) and step (b) such that the probes are hybridizing to the *same* target sequences that are part of step (a) and step (b). In other words, regardless of whether one does step (b) before step (a), the target sequences in step (b) are the *same* as those from step (a).” Cooper Decl. ¶ 12 (emphasis added). This statement is further support that the claim requires steps (a) and (b) be performed sequentially because if the target sequences are the same, they must have already been provided in step (a) before step (b) can be completed.

In sum, the intrinsic evidence requires that step (a) be performed before step (b). Consequently, step (d) also cannot be performed before step (a).¹² In light of such a construction, Illumina requests that the Court reconsider its order denying the motion to amend infringement contentions. See Pls.’ MTS Opp’n at 8 n.3. “A claim construction by the Court different from that proposed by the party seeking amendment” may support a finding of good cause, absent

¹² This is not to say that the entire claim must be performed sequentially. The Court’s holding is limited to the order of step (a) in relation to steps (b) and (d).

undue prejudice to the non-moving party. Patent L.R. 3-6. However, that is not the case here. Rather, it would be unduly prejudicial to allow a new infringement theory at this late stage. *See Karl Storz Endoscopy-Am. v. Stryker Corp.*, No. 13-0876-RS (JSC), 2016 U.S. Dist. LEXIS 176876, at *8 (N.D. Cal. Dec. 21, 2016) (“Prejudice is typically found when amending contentions stand to disrupt the case schedule or other court orders.”). The request to reconsider the order denying Illumina’s motion to amend its infringement contentions is DENIED.

B. Harmony V1: Infringement of Step (a)

Ariosa argues that Harmony V1 does not practice step (a) of Claim 1. According to Ariosa, in Harmony V1, single-stranded cfDNA (the alleged “target sequences”) is introduced into the sample simultaneously with the oligos (the alleged “probes”) and streptavidin beads (the alleged “first solid support”). Def.’s MSJ at 7. Because the cfDNA is introduced separately from the streptavidin beads, Ariosa argues that Harmony V1 does not practice step (a)’s requirement that the method begin with a sample of single-stranded target sequences already attached to a first solid support. *Id.* at 9.

This argument fails for two reasons. First, the description of Harmony V1 is disputed. *See* Pls.’ MSJ Opp’n at 24-25. As described in Illumina’s expert report, “cfDNA (black) is labeled with a biotin (B) moiety . . . and is immobilized onto . . . streptavidin (SA)-coated magnetic beads. Trios of DANSR oligos (orange) specific for each of the selected loci are *then* annealed to the immobilized cfDNA.” Corrected Cooper Report ¶ 86 (quoting Ariosa’s “Overview of Harmony Prenatal Test”; emphasis added); *see also* Pls.’s MSJ Opp’n at 3 (describing Harmony V1 as first attaching cfDNA to beads, then hybridization); Hearing Tr. at 75:2-5; *but see* Corrected Cooper Report ¶ 90. From this passage, it appears that cfDNA is immobilized on streptavidin beads before the oligos anneal to the cfDNA. This factual dispute makes summary judgment inappropriate. Second, even if the cfDNA, oligos, and streptavidin beads are added simultaneously, the Court disagrees with Ariosa’s analysis. As discussed above, step (a) includes an attachment step, so the cfDNA need not already be attached to streptavidin beads before the

sample is provided. Therefore, the Court DENIES summary judgment of non-infringement of Harmony V1.

C. Harmony V2: Infringement of Steps (a) & (b)

Ariosa also argues that Illumina cannot show that Harmony V2 infringes either steps (a) or (b) of claim 1. In Harmony V2, single-stranded cfDNA is biotinylated and then incubated with oligos. During this incubation, the cfDNA and oligos form double-stranded hybridization complexes. Streptavidin beads are added after the hybridization complexes are formed. Corrected Cooper Report ¶¶ 232-234. Ariosa argues that because the hybridization complexes are formed before attachment to the streptavidin beads, Harmony V2 does not practice either step (a) or step (b). Illumina responds that even if steps (a) and (b) must be performed sequentially, there is still an issue of material fact as to infringement. Pls.'s MSJ Opp'n at 16-17. In particular, Dr. Cooper opines:

[E]ven if one posits that the order of steps (a) and (b) of Claim 1 is essential to the methodological definition of claim 1, at least 100 of the target sequences would almost certainly exist in the single-stranded form even after the oligonucleotide probes are allowed to anneal to the target sequences for 2 hours, and only become bound to oligonucleotide probes after mixing with and attaching to SA beads. This is a result of the sheer numbers of fragments and target sequences involved, the complexity of the solution in which target sequences and probes are mixed, and reaction dynamics.

Corrected Cooper Report ¶ 240. In light of this factual dispute, the Court DENIES summary judgment of non-infringement on this ground.

D. Harmony V2: Infringement of Steps (f) and (g)

Ariosa further argues that Harmony V2 does not practice steps (f) or (g) of Claim 1 because the Readout Cassettes do not meet the definition of an "amplicon," [REDACTED]. Claim 1 recites:

d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes;

e) contacting said modified probes with:

- i) at least a first primer that hybridizes to said universal priming site;
- ii) NTPs; and
- iii) an extension enzyme;

wherein said different modified probes are amplified and forming different amplicons;

f) immobilizing said different amplicons to a second solid support, and

g) detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences.

The '794 Patent, 68:65 – 69:12. The Court construed “wherein said different modified probes are amplified and forming different amplicons” to mean: “wherein the different modified probes are replicated, in whole or in part, to yield amplification products of each of the different modified probes.” Claim Construction Order at 11.

United States District Court
Northern District of California

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

[REDACTED]

[REDACTED]

Ariosa claims that Harmony V2 does not meet steps (f) or (g) because the amplification products are cleaved to create “Readout Cassettes” before immobilization to the microarray (the alleged “second solid support”) and before detection. Def.’s MSJ at 19. This argument hinges on a finding that Readout Cassettes are not “amplicons” under the Court’s claim construction. But whether the Readout Cassettes are “amplicons” under a doctrine of equivalents theory is disputed, and is for the fact finder to resolve. *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1302 (Fed. Cir. 2011) (there may be a factual issue where “the claim construction itself is not contested, but the application of that claim construction to the accused devise is.”). Therefore, the Court DENIES summary judgment of non-infringement of step (f) and step (g) on this ground.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

41

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In sum, Ariosa has not met its burden to show that summary judgment is appropriate. There are disputes of fact as to whether the accused products perform the limitations at issue. Therefore, the Court DENIES Ariosa's motion for summary judgment.

CONCLUSION

For the foregoing reasons, Plaintiffs' anti-SLAPP motion to strike Ariosa's counterclaims and motion for summary judgment are GRANTED in part and DENIED in part. Ariosa's motion to strike portions of the Corrected Expert Report of Dr. Cooper is GRANTED in part and DENIED in part. Ariosa's motion to preclude testimony by Dr. Cooper is DENIED. Ariosa's motion for summary judgment is DENIED. In light of the numerous materials filed under seal, the Court directs the parties to file a joint statement requesting that certain portions of this order be redacted **within two weeks of this order**. Otherwise, the order will be filed publicly in its entirety at that time.

IT IS SO ORDERED.

Dated: December 11, 2017



SUSAN ILLSTON
United States District Judge